Remarks

By the foregoing amendment, claims 22 through 31 are new. Applicants respectfully submit that no new matter was added by the amendment, as all of the claimed subject matter was either previously illustrated or described in the drawings, written specification and/or claims of the application. Entry of the amendment and favorable consideration thereof is earnestly requested.

For the reasons stated below Applicants respectfully submit that all pending claims are allowable over the reference of record, and earnestly solicit allowance of the same.

Rejected Claims

The examiner has rejected claims 1 through 21 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,954,747 to Clark ("Clark"). The Applicants respectfully submit that Clark does not anticipate the claimed invention because Clark is missing a shoulder formed between the distally projecting single point and a remaining part of said front face as required by all pending claims.

Summary of the Prior Art and Disclosed Invention

Clark discloses a meniscus repair anchor system. The system comprises a hollow needle 52 for inserting an anchor into the meniscus. The anchor is enclosed in the hollow needle. The distal end of the needle is inserted into the meniscus. When the needle is inserted entirely through the meniscus the anchor is deposited and the needle is withdrawn. The hollow needle has a front annular face at its distal end. (Fig. 3.) The plane of the front annular face is at an angle of approximately 45 degrees to longitudinal axis of the hollow needle. (Fig. 3.) This configuration allows the distal end of the hollow needle to easily penetrate the meniscus. The front annular face further includes a point.

(Fig. 3.) This protruding point also allows the needle to more easily penetrate the meniscus.

The present invention relates to a device for introducing a suture thread anchor into bone. A typical use for such device includes the introduction of a suture thread anchor into bone to repair shoulder injuries and instabilities. (Par. 5). The device comprises a hollow guide sleeve with an annular face at its distal end. A single point projects distally from the front face of the guide sleeve. The distal end of the hollow guide sleeve is contoured so that it is possible for the distal end to be applied to the bone with greater versatility, but without the risk of it sliding away from the bone. (Par. 16).

More specifically, as shown below:

> The outermost point 45 lies . . . on an outer circumference line 46 of the tube 32. The bevelled cut 44 is so configured that it encloses an angle of about 30° to the longitudinal axis 39. The angle of the bevelled cut 44 and also the circumferential extent of the point 40 can vary, <u>although it must always be ensured that a shoulder 48 is formed between the point 40 and the front annular face 36</u>.

(Par. 59)(emphasis added.)

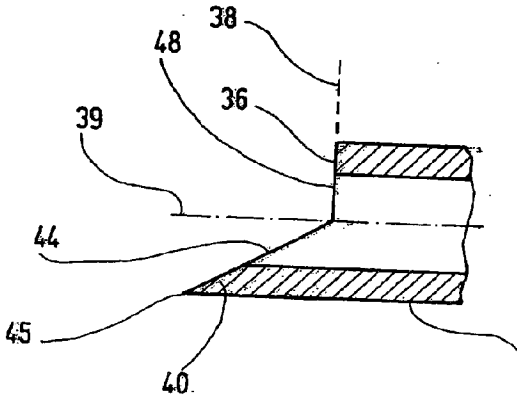

Fig.6

By means of the shoulder 48, the device is applied with a secure fit to the bone. (Par. 60.) At the same time the entire device can still be positioned, for example by pivoting it to the left or right in the plane of the drawing or by pivoting it towards or away from the person looking at this drawing. In this way, an ideal position can be found for positioning the suture thread anchor, while at the same time ensuring the distal end of the guide sleeve is securely fit to the bone.

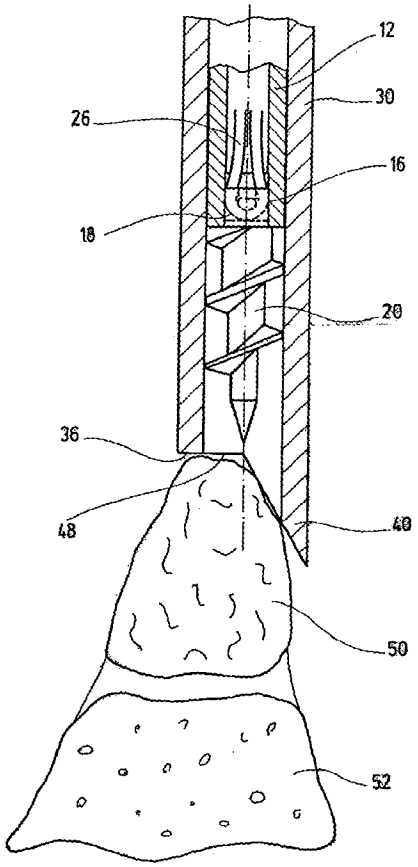

Fig.7

Argument

The Applicants respectfully submit that Clark does not anticipate the claimed invention because Clark does not disclose all of the elements required by every pending. Clark is missing a shoulder formed between the distally projecting point and the remaining part of the front annular face. This limitation is required by claims 1 through 21. A shoulder is a transition via a corner or an edge. As discussed above, the shoulder allows the surgeon to securely fit the distal end of the guide sleeve to the bone, while still allowing the surgeon to alter the angle of the hollow guide sleeve. Clark does not anticipate the present invention because it does not disclose a transition via a corner or an edge between the projecting point and the front face.

As show in the figure below, Clark has straight or smooth transition between the projecting point and the front annular face.

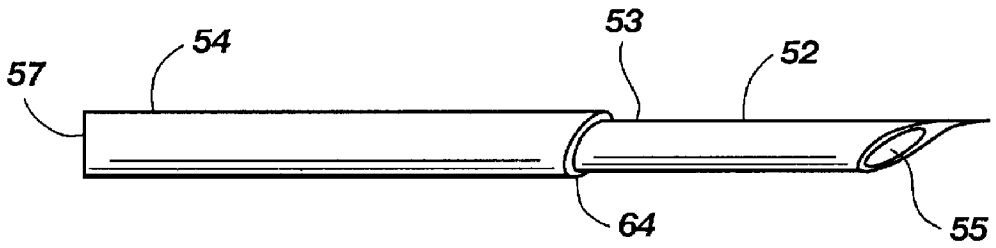

Fig. 3

The straight or even transition between the distal point and the front face in Clark allows the surgeon to more easily insert the hollow needle into the meniscus tissue. As the hollow needle is inserted, the diameter of the needle gradually increases along the longitudinal axis because the plane of the annular face is at approximately a 45 degree angle to the longitudinal axis. This configuration allows the surgeon to more easily insert the needle and minimize tissue damage. If Clark included a shoulder, as disclosed in the present invention, the diameter of the hollow needle would abruptly increase

along the longitudinal axis at the shoulder. Such an abrupt increase would make the needle more difficult to insert into the tissue, and would cause unnecessary damage to the tissue.

There is not motivation to modify the distal end of the needle in Clark to include a shoulder as required by all pending claims because Clark is designed to easily penetrate soft tissue. Clark teaches that that a straight or smooth transition between the distal point and front face decreases the resistance when the needle is inserted into the soft tissue, and minimizes unwanted tissue damage. One of ordinary skill in the art would not be motivated to add a shoulder to the distal end of the needle because such a feature would increase resistance during insertion, and cause unwanted damage to the soft tissue.

The present invention, on the other hand, is directed to providing a hollow guide sleeve that can be securely fit to the bone, while still allowing the surgeon to pivot the guide sleeve about its distal end. To accomplish this, the present invention includes a shoulder at the distal end of the guide sleeve to obtain a secure fit to the bone. In this way, an ideal position can be found for positioning the suture thread anchor while at the same time ensuring a secure fit with the bone. Thus, Clark teaches away from the present invention.

Furthermore, one of ordinary skill in the art would not be motivated to modify the needle of Clark to arrive at the present invention because Clark and the present invention are directed to solving different problems. Clark is directed to penetrating soft tissue. The present invention, on the other hand, is directed to securing or fixing to hard tissue.

New Claims

Applicants have added new independent claim 22 and depending claim 23 through 31. Applicants respectfully submit that the new claims are patentable of Clark. Independent claim 22 requires all of the limitations of independent claim 1, and therefore is patentable over Clark as discussed above. In addition, claim 22 requires that the front annular face is approximately perpendicular to a longitudinal axis of the guide sleeve with the exception of said single point and said shoulder.

In addition to the reasons stated above, Clark does not anticipate independent claim 22 because it is missing the limitation that the front annular face is approximately perpendicular to a longitudinal axis of the guide sleeve. Clark discloses that the front annular face is at an angle of approximately 45 degrees to the longitudinal guide axis. As discussed above this configuration gradually increases the diameter of the needle as down the longitudinal axis. As a result, the Clark needle more easily penetrates the meniscus, and minimizes unwanted soft tissue damage. Furthermore, as discussed above, it would not be obvious for a person having ordinary skill in the art to modify the Clark front annular face to be perpendicular to the longitudinal axis of the guide sleeve because such a modification would only make the needle more difficult to insert into soft tissue, and would cause unwanted tissue damage.

For the foregoing reasons, the Applicants respectfully submit that all pending claims are allowable over the reference of record, and earnestly solicit allowance of the same.

Respectfully submitted,

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